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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/602,981

06/24/2003

John D. Roback

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EXAMINER

HANDY, DWAYNE K

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

01/24/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/602,981

Applicant(s)

ROBACK ET AL.

Examiner

Dwayne K. Handy

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3,5,8,10-13,15,18-29,31,33,35-45,47 and 48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 15,18-22 and 39-45 is/are allowed.
- 6) ☒ Claim(s) 1,3,5,8,10-13,23-29,31,33,35-38,47 and 48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1, 3, 5, 8, 10-13 and 47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1 and 47 contain the limitation of "the sample separation system" but lack antecedent basis for this limitation

3. Claims 23-29, 31, 33, 35-38 and 48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 23 and 48 contain the limitation of the filter material causing the reacted components in the sample to spread out evenly over the top surface of the material. Claim 23 contains the additional limitation of the filter substantially preventing interacted components from passing through it. While these limitations may be found in other claims that have not been rejected, claims 23 and 48 also contain the limitation of the filter material having a pore size "from about 0.1 microns to about 3 microns". In the Specification (page 11, lines 11-20), Applicant has disclosed that the pore size required to cause the sample to spread across the filter is approximately 0.2 microns to approximately 1.2 microns. Therefore, it is unclear to the Examiner as to how a filter having a pore size greater than

1.2 microns can meet the limitation of the filter spreading across the filter. The Examiner submits that a pore size greater than 1.2 micron would not allow for the sample to be spread out over the surface of the filter as required by the claim.

***Allowable Subject Matter***

4. Claims 15, 18-22 and 39-45 are allowed.

5. The following is a statement of reasons for the indication of allowable subject matter: Claim 39 recites a methods for immunological assay that includes the steps of providing a vessel bottom having an uneven surface and filter, mixing a sample with a reagent in the vessel, spreading the sample mixture over the top surface of the filter material while preventing reacted components from passing through the filter, and analyzing the sample mixture by flow cytometry to determine the presence of evidence of agglutination reactions. ***The filter material provides the uneven surface and is configured to spread the sample mixture over the top surface of the filter material while preventing reacted components from passing through the filter.***

Claim 15 recites an immunological assay system. The system is comprised of a vessel for containing an assay sample, an incubator, a dilute concentration of sample, a dilute concentration of reagent, an image acquisition system designed to detect the presence of evidence of agglutination reactions consisting of a flow or capillary cytometer in close proximity to the sample, and a centrifugation system. ***The filter material provides the uneven surface and is configured to spread the sample***

***mixture over the top surface of the filter material while preventing reacted components from passing through the filter.***

The Examiner considers Yaremko to be the closest prior art. Yaremko teaches a method and system having a microcolumn for separation, incubator, centrifuge and imaging system but does not teach the filter material as claimed by Applicant in the amended claims.

6. Claims 1, 3, 5, 8, 10-13, 23-29, 31, 33, 35-38 and 47 would be allowable if properly amended to overcome the 112, 2<sup>nd</sup> Paragraph rejections listed above. Claims 1, 47 and 48 recite assay systems similar to that of claim 15 that contain the filter limitation cited in bold above. The prior art does not contain nor suggest the filter limitation. Claim 23 recites a method similar to that of claim 39 that includes use of the filter.


**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dwayne K. Handy whose telephone number is (571)-272-1259. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DKH  
January 22, 2008

  
LYLE A. ALEXANDER  
PRIMARY EXAMINER